REMARKS

On page 2 of the Office Action, the Examiner objects to Claims 17, 20-22 and 24-26 because the claims allegedly contain typographical errors and because the preambles of the dependent Claims 20-22 and 25-26 are allegedly inconsistent with the claims from which they depend.

In view of the amendments to the claims, Applicants respectfully submit that the Examiner's objection has been rendered moot.

On page 3 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

Specifically, the Examiner states that the claims are drawn to a method of detecting BDV infection in a subject, but that the specification only discloses detection of IgM and IgG antibodies that bind BDV (i.e., not a method of detecting BDV infection).

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (*In re Wertheim*, 541 F.2d 257, 263 (1976)). The Examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims (MPEP §2163).

Applicants respectfully submit that the specification explicitly discloses methods for the detection of a BDV infection vis-à-vis the presence of IgM and/or IgG specific thereto. See paragraphs 51-54 of the corresponding patent publication, which state in pertinent part:

> upon infection with a virus or the like that is an exogenous antigen, IgM first is raised, then an IgG antibody is raised while gradual decrease of the amount of the IgM...as a consequence of the study of a certain type of viruses, particularly, a slight amount of viruses, the present inventors found cases in which the class switching from IgM to IgG requires one year or longer. In such instances, it is probable that early stages of viral infections are overlooked when IgG alone is measured. Thus, the present inventors investigated method for carrying out the examination of a disease caused by an exogenous antigen in a more accurate manner, which enables the measurement of an antibody also in the early stage of the infection, in which the IgM is detected... Specific examples of the exogenous antigen to which the method for detecting an antibody according to the present invention may be applied include some types of viruses...such viruses include BDV…that infects nerve cells and requires a long period of time for the class switching from IgM to IgG. (Emphasis added)

Furthermore, Carbone, cited by the Examiner in the present Office Action, page 4, states, "when [an] individual contracts a virus infection, the first serological evidence of virus infection is often the immunoglobulin M (IgM) antibody. As the immune response matures, an antiviral IgG antibody response is detected" (page 516, Anti-BDV antibody detection). In addition, Carbone states, "a significant increase in the titer of virus-specific IgG from the acute-phase to the convalescent phase serum sample is indicative of infection." *Id.* Thus,

Carbone proves the opposite of that which the Examiner concludes - that the presence of serum IgM and IgG to BDV are indicative of infection.

The Examiner has failed to overcome the strong presumption that an adequate written description of the claimed invention is present when the application was filed because a person skilled in the art would readily appreciate that the specification explicitly discloses methods for the detection of an infection by BDV vis-à-vis the presence of IgM and/or IgG specific thereto, which constitutes adequate support for the claims.

Accordingly, Applicants request withdrawal of the Examiner's rejection.

On page 3 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 112, first paragraph as lacking enablement.

Specifically, the Examiner states that while the specification enables a method of detecting antibodies that bind BDV, the Examiner alleges that the specification does not enable a method of detecting a BDV infection. The Examiner attempts to buttress the rejection by reliance on Carbone, which he concludes is evidence that viruses may or may not be present in subjects that have anti-serum, because some viruses are cleared while others persist and because the detection of anti-BDV antibodies is not correlated to an acute or latent BDV infection (Carbone, page 516, top of second column). The Examiner therefore concludes that it requires undue experimentation to determine if a subject is infected with BDV based on Applicants' teachings.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures coupled with information known in the art, without undue experimentation.

Applicants respectfully submit that the claims explicitly recite "infection" in the preamble, support for which is found in the specification which explicitly teaches how to perform methods for the detection of an infection by BDV vis-à-vis detecting the presence of IgM and/or IgG specific thereto (see paragraphs 51-54 of the corresponding patent publication).

Regarding Carbone, as noted above, the state of the art indicates the opposite of that which the Examiner concludes - that the presence of serum IgM and IgG to BDV are indicative of infection. The Examiner's conclusion that viruses may or may not be present in subjects that have anti-serum is illogical and inconsistent with the cited reference because the Examiner analogizes "infection" with "stages of infection". The claims do not refer to detecting a particular "stage of infection". Thus, the Examiner's comments are irrelevant. Based on Applicants' specification and the state of the art, Applicants respectfully submit that one of skill in the art would appreciate the well-established correlation between Ig production and BDV infection such that only routine laboratory work is required to perform the claimed method of infection detection.

Applicants respectfully submit that one skilled in the art could perform the present invention routinely because of the

explicit disclosure of BDV polypeptides and detection methods therefor explicitly disclosed in the specification, coupled with the common knowledge in the art (e.g., Carbone).

Accordingly, Applicants request withdrawal of the Examiner's rejection.

On page 5 of the Office Action, the Examiner rejects Claims 17, 20-22 and 24-26 under 35 U.S.C. § 103(a) as being unpatentable over Yamaguchi et al in view of Watanabe et al, as evidenced by Planz et al further in view of Hatalski et al and Carbone.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The Examiner admits that Yamaguchi et al fails to disclose p10, as claimed. While Yamaguchi et al may disclose ECLIA methods for detecting p40 and p24, Yamaguchi et al states, "the ECLIA would serve as an excellent screening test to detect BDV antibodies *when combined with more specific tests such as WB analysis* or the binding inhibition assay based on the addition of specific BDV peptides" [emphasis added] (page 354, Discussion). Thus, according to Yamaguchi et al, the method of Yamaguchi et al cannot possibly be used alone to accurately assess BDV infection.

Watanabe et al fails to cure the deficiencies of Yamaguchi et al. Watanabe et al discloses only WB (Fig. 2). Applicants' ECLIA method cannot be rendered obvious by Watanabe et al because the reference clearly states, "the results in this study [the detection of antibodies to BDV by WB] could be worthy for the establishment of diagnostics methods for BDV infection..." (page 777). The results obtained by

Watanabe et al are therefore self-limiting (i.e., to BDV polypeptide detection by WB analysis). This is consistent with the disclosure of Yamaguchi et al, which clearly states that ECLIA must be combined with WB in the detection of BDV.

Thus, the Examiner's argument that ECLIA using p10, p24 and p40 is obvious in light of the cited references is clearly incorrect. The Examiner's legal conclusion is also incorrect. The disclosures of Yamaguchi et al and Watanabe et al fail to teach each and every element of the claimed invention, and actually teach away from the Applicants' highly sensitive method of detection of BDV infection using ECLIA for p10, p24 and p40.

Furthermore, Planz et al, Hatalski et al and Carbone do not remedy the deficiencies of Watanabe et al and Yamaguchi et al.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested by Yamaguchi et al, alone or in combination with Watanabe et al, Planz et al, Hatalski et al or Carbone. Thus, Applicants request withdrawal of the Examiner's rejection.

In view of the amendments to the claims and the arguments set forth above, reconsideration and allowance of this application are respectfully requested.

The Examiner is invited to contact the undersigned at the below listed number on any questions which might arise.

Respectfully submitted,

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